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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,420	09/27/2001	Wouter E. Roorda	50623.00140	6380

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Squire, Sanders & Dempsey L.L.P.
Suite 300
One Maritime Plaza
San Francisco, CA 94111

EXAMINER	
MICHENER, JENNIFER KOLB	
ART UNIT	**PAPER NUMBER**
1762	

DATE MAILED: 10/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/966,420	ROORDA ET AL.	
	Examiner	Art Unit	
	Jennifer Kolb Michener	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 16-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 September 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-14 and 16-20, drawn to a method of tumble coating, classified in class 427, subclass 242.

   II. Claim 15, drawn to a product by process, classified in class 623, subclass 1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process, such as dipping or electrocoating.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Victor Repkin on 3/25/2002 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-14 and 16-20. Affirmation of this election must be made by applicant in replying to this Office action. Claim 15 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1, 3, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by De Leon et al. (4,952,419).

De Leon teaches tumbling medical implants in a coating pan to coat with a sprayed coating substance (abstract; col. 3, line 57; col. 4, lines 1-10; Example 1).

10. Claims 1-3 and 7-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Schwarz et al. (US 6,368,658 B1).

Schwarz et al. teaches a method for coating implantable medical devices (col. 2, line 1) comprising tumbling the devices in a coating chamber (see Figures) and introducing a coating substance to said chamber to coat said implantable devices (col. 2, line 4).

Regarding claim 2, Schwarz teaches coating stents in the method set forth above (col. 3, line 48).

Regarding claim 3, Schwarz teaches that there is a rotating, planar, metal or ceramic plate in the lower portion of the chamber, from which the medical devices are repeatedly bounced during the coating operation (col. 7, line 64; col. 8, lines 5, 9, 26, 58, and 65). This plate acts as a coating pan as required by Applicant.

Regarding claim 7, Schwarz teaches spraying a coating substance onto the uplifted, tumbling medical device (see Figures; col. 8, line 30; col. 9, line 34; Example 1; throughout).

Regarding claims 8-10, Schwarz teaches that the coating substance may be a polymer dissolved in a fluid (Example 1; throughout) with an active agent, such as rapamycin (col. 4, line 37).

Regarding claims 11-14, Schwarz teaches the use of jets of air (abstract; throughout), which will inherently aid in drying volatile coating solvents. Example 1 outlines a process in which the medical devices are subjected to air, a gaseous composition, at a temperature of 20-90 °C before the coating step, which heats the medical devices prior to coating, as required by claim 14 and provides air within the temperature range claimed by Applicant in claim 13. Additionally, Schwarz teaches a process temperature of 0-200 °C (col. 9, line 62), which would heat both the substrates and the air.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 1-14 and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwarz et al. (6,607,598) in view of Forster (4,581,242).
Schwarz '598 teaches a substantially similar method as disclosed by Schwarz '658, above, i.e., a method of coating medical devices, such as stents, in a coating chamber using spray coating techniques.
In addition, regarding independent claim 16, Schwarz '598 teaches that medical devices may be coated by pan-coating operations (col. 17, lines 35-40), but Schwarz fails to specifically teach the elements of a pan coating operation. It would have been obvious to one of ordinary skill in the art to look to the art of pan-coating for such elements to perform the operation disclosed by Schwarz '598.

Forster is cited for teaching the coating of pharmaceutical substrates and other small articles (col. 1, line 68) using a pan coating method (col. 2; throughout).

The pan of Forster, with articles to be coated therein, is rotated about a rotating axis (col. 2, line 27) and is shown in the Figures to be tilted at about 45 degrees with respect to the horizontal plane, which is an acute angle. A coating substance is sprayed into the rotating pan onto the tumbling articles (col. 2, line 57).

Since Schwarz '598 teaches coating stents, which are small articles, in pan-coating operations and Forster teaches that pan coaters are useful in coating small articles by tilting the pan, rotating about an axis, and spraying the coating composition therein, Forster would have reasonably suggested the specifics of his pan-coating method in the pan-coating method of Schwarz. It would have been obvious to one of ordinary skill in the art to use the teachings of Forster in the method of Schwarz to provide Schwarz '598 with a suitable procedure for pan coating small articles such as stents because Forster's method is suitable for small articles useful in the medical field where precise dosing and sterile conditions are required.

Regarding claims 17-18, Schwarz teaches coating stents with polymers dissolved in solvents with active agents (col. 6, Example 1).

Regarding claim 19, Schwarz '598 and Forster both teach the use of air blown into the coating pan.

The elements of claim 20 have been outlined above.

Regarding the first set of claims (1-14), Schwarz '598 teaches the elements of these claims in the same manner as outlined above in the '658 rejection. The limitations of claims 4-6 requiring specifics of the pan coating have been outlined above, in this rejection relating to the latter set of claims. Regarding the limitation of claim 6 requiring a specific rotation speed, not addressed above, it is Examiner's position that selection of an optimum rotation speed would have been within the skill of an ordinary artisan depending on the durability of the substrate, the number of articles contained within the pan, and the desired speed of coating.

It is well settled that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Conclusion

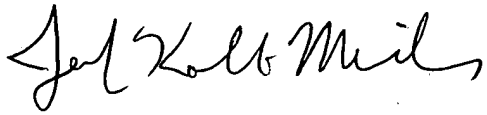
15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hansen et al. teaches a method of pan coating medical implants using spraying and rotation. Laube teaches pan-coating medical implants. Williamitis teaches tumbling catheters with coating solution.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number is 703-

306-5462. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



Jennifer Kolb Michener
Patent Examiner
Technology Center 1700
October 1, 2003